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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,506	09/14/2001	Andreas Huth	SCH-1806	5688
23599	7590 06/12/2002			
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400			EXAMINER	
			LIU, HONG	
ARLINGTON	ARLINGTON, VA 22201			PAPER NUMBER
			1624	
•			DATE MAILED: 06/12/2002	, !!

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/831,506

Applicant(s)

Huth et al.

Examiner

Hong Liu

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- The MAILING DATE of this communication appears on the cover sheet with the corres	spondence address				
P riod for Reply	THICK EDOM				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.					
- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after	SIX (6) MONTHS from the				
mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be consi					
 If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing dat Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C.) 	§ 133).				
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce earned patent term adjustment. See 37 CFR 1.704(b).	any				
Status					
1) Responsive to communication(s) filed on					
2a) ☐ This action is FINAL . 2b) ☒ This action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution closed in accordance with the practice under Ex parte Quay(835 C.D. 11; 453 O.G. 2)					
Disposition of Claims					
4) 💢 Claim(s) <u>1-15</u>	is/are pending in the applica				
4a) Of the above, claim(s) <u>13-15</u>	_ is/are withdrawn from considera				
5)	is/are allowed.				
6) 🗓 Claim(s) <u>1-12</u>	is/are rejected.				
7)	is/are objected to.				
8) Claims are subject to	restriction and/or election requirem				
Application Papers					
9) The specification is objected to by the Examiner.					
10) The drawing(s) filed on is/are a accepted or b) objected	d to by the Examiner.				
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CF	R 1.85(a).				
11) The proposed drawing correction filed on is: a pproved	b)⊡disapproved by the Examiner.				
If approved, corrected drawings are required in reply to this Office action.					
12) The oath or declaration is objected to by the Examiner.					
Priority under 35 U.S.C. §§ 119 and 120					
13) 🛛 Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) o	r (f).				
a)⊠ All b) ☐ Some* c) ☐None of:					
1. ☐ Certified copies of the priority documents have been received.	·				
2. ☐ Certified copies of the priority documents have been received in Application No	·				
 Copies of the certified copies of the priority documents have been received in this application from the International Bureau (PCT Rule 17.2(a)). 	National Stage				
*See the attached detailed Office action for a list of the certified copies not received.					
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).					
a) The translation of the foreign language provisional application has been received.					
15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/	or 121.				
Attachment(s)					
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PT 3) Notice of Informal Patent Application (PT 6) Other:	O-152)				
3) XInformation Disclosure Statement(s) (PTO-1449) Paper No(s)					

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DETAILED ACTION

Claims 1-15 are pending in this application.

1.

Election/Restriction

Applicants's election of the group wherein A, Z, and R1 do not form a single group and A is NR2, and Z is the group having the formula in the second line of page 77 along with the species No. 2.54 is acknowledged. Applicants are expected to amend the claims such that the claims will be commensurate to the scope of the elected subject matter in case it is found allowable. Claims 13-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 7, 9-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

2. 1). Claims 9 and 10 are substantial duplicates of Claim 8, as the only difference is intended use which is not given material weight. Note In re Tuominen 213 USPQ 89.

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2). Claims 7, 11, and 12 provide for the use of the compound, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 7, 11 and 12 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

- 3). Claim 2 recites the limitation R1 being phenyl or pyridyl substituted with one or more places with alkyl, hydroxy, halogen, etc. There is insufficient antecedent basis for this limitation in the claim. In claim 1, the heteroaryl in the meaning of R1 can only be substituted with alkoxy.
- 4). Claim 1 is vague and indefinite in that the language is unclear whether R1 is alkyl substituted with aryl or heteroaryl or R1 can also be aryl and heteroaryl.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Ozaki et al. (US Patent 5,716,993). Ozaki teaches the compound and composition of the instant invention (see Example 33, col 57).

Claims 1-6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Schipper et al. (US Patent 3,226,394). Schipper teaches the compound and composition of the instant invention (see Examples, in particular 2-β-(4-pyridyl)ethylamino-4,5-dimethoxybenzamide.).

Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ozaki et al. (US Patent 5,716,993).. Ozaki et al. teach a generic group of anthranilic acid derivatives (See col. 1.), in particular, where Y is oxygen or sulphur, W is N or C, A represents a group of formula -X-CH2-Z wherein X can be CH2, and Z can be an optionally substituted aryl or heteroaryl group, etc. In addition to compound 33 which anticipates the claims as discussed in the above 102 rejection, compounds 41 and 82 differ from the claimed compounds only in the nature of substituent for X. However, the compounds of the instant invention are generically embraced by the reference in view of the equivalence of C(O) and CH2. Thus, one of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the

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reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. See *In re Susi*, 440 F.2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. V. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

Claims 1-6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schipper et al. (US Patent 3,226,394). The reference teaches a generic group of compounds which embraces applicant's instantly claimed compounds. See formula I, Col. 1 wherein Py is pyridyl and R1 is a monovalent lower hydrocarbon radical, etc. The compounds are taught to be useful as pharmaceutical agents. The claims differ from the reference by reciting a specific species and/or a more limited genus than the reference. However, it would have nevertheless been obvious to one skilled in the art at the time of the invention to be motivated to select any of the species of the genus taught by the reference including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the specie of the genus would have similar properties and, thus, the same use as taught for the genus as a whole. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 09/850,434. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patents contain subject matter that overlaps with that embraced by the instant claims.

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This is a provisional obviousness-type double patenting rejection because the conflicting

claims have not in fact been patented.

Any inquiry concerning this communication should be directed to Examiner Hong Liu

whose telephone number is (703) 306-5814. The examiner can normally be reached on Monday

through Friday from 8:30 AM to 6:00 PM. If attempts to reach the examiner by the phone are

unsuccessful, the examiner's supervisor, Mukund Shah can be reached at (703) 308-4716. The

fax phone number for this group is (703) 308-4734 for "unofficial" purposes and the actual

number for official business is (703) 308-4556. Any inquiry of a general nature or relating to the

status of this application or proceeding should be directed to the Group receptionist whose

number is (703) 308-1235.

June 10, 2002

Muxund J. Had

Mukund Shah

Supervisory Patent Examiner

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